REMARKS

This Amendment is submitted in response to the Office Action mailed February 10, 2009. Claims 1 and 6 are currently pending in the application. Claims 7-11 were previously withdrawn.

CLAIM OBJECTIONS

Claim 1 is objected to for reciting the term "resulting from ..." Claim 1 has been amended herein deleting the term "resulting from", thereby mooting the objection to claim 1.

REJECTION UNDER 35 U.S.C. §112 SECOND PARAGRAPH

The Examiner rejected claims 1 and 6 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. More specifically, the Office Action alleges that the term "elevated nutrient intake" is unclear and that the specification does not define the term.

The applicants disagree with any alleged indefiniteness, however, claims 1 and 6 have been amended to expedite prosecution of the application. More particularly, claim 1 has been amended to recite "[a] pharmaceutical combination useful to suppress the appetite of a subject, the combination comprising Gly_2GLP-2 and exendin (9-39)." Claim 6 has been amended to recite "[a] kit comprising a pharmaceutical combination as defined in claim 1, and instructions for the use thereof to suppress the appetite of a subject."

Support for the amendments may be found throughout the specification as published including paragraphs [0014], [0031], [0048] and [0052]. More specifically, the term "appetite suppression", as discussed in paragraph [0048], is a reduction in food intake in treated subjects relative to an untreated control group.

Applicants submit that the claims are definite and particularly point out and claim the invention. As such, applicants respectfully request the removal of the rejection of claims 1 and 6 under 35 U.S.C. §112, second paragraph.

REJECTION UNDER 35 U.S.C. §112 FIRST PARAGRAPH

The Examiner rejected claims 1 and 6 under 35 U.S.C. §112, first paragraph, as allegedly containing new matter. Applicants disagree with the alleged new matter rejection, however, to further prosecution in this case, claims 1 and 6 have been amended herein. More specifically, claim 1 has been amended to recite "[a] pharmaceutical combination useful to suppress the appetite of a subject, the combination comprising Gly_2GLP-2 and exendin (9-39)." As discussed previously, support for the claim amendments may be found throughout the specification including paragraphs [0014], [0031], [0048] and [0052], as published. In particular, paragraph [0048] teaches that "appetite suppression" may be shown as a reduction in food intake in treated subjects relative to an untreated control group. Therefore, amended claims 1 and 6 are supported by the original disclosure and, as such, do not include any new matter. Accordingly, applicants request the removal of the rejection of claims 1 and 6 under 35 U.S.C. § 112, first paragraph.

Claims 1 and 6 remain rejected under 35 U.S.C. §112, first paragraph, allegedly because the specification, while being enabling for claims limited in scope to a pharmaceutical composition comprising Gly_2GLP-2 and exendin (9-39), and a kit thereof, for the use of reducing or inhibiting food intake or suppressing appetite in mice by intracerebroventricular injection or central administration, does not reasonably provide enablement for claims to said pharmaceutical composition for the use of treating a medical condition, disorder or disease resulting from elevated nutrient intake or any/all types of body weight control disorders.

While applicants do not agree with any alleged lack of enablement, claims 1 and 6 have been amended herein to further prosecution of the application. Claim 1 has

been amended to recite "[a] pharmaceutical combination useful to suppress the appetite of a subject, the combination comprising Gly_2GLP-2 and exendin (9-39)." Claim 6 has been amended to recite "[a] kit comprising a pharmaceutical combination as defined in claim 1, and instructions for the use thereof to suppress the appetite of a subject."

As discussed on pages 4 and 5 of the previous Amendment and Response, mailed July 9, 2008, the claims are supported by the specification including the disclosure of various dosing strategies for use in humans. For example, paragraphs [0036] through [0045] of the application as published, disclose dosing strategies for exendin and GLP-2 based on published references and animal and human studies. More particularly, the specification discloses dosing appropriate for subcutaneous and intravenous administration, delivery directly to the central nervous system, oral administration and parenteral administration. Furthermore, paragraph [0069] discusses the reduction of appetite and meal size by peripheral administration of GLP-2 in human subjects. Moreover, the specification provides specific examples of dosing in animal experiments using well accepted animal models. On page 5 of the Office Action, the Examiner alleges that intracerebroventricular peptide injections are not suitable for treating other animals or humans. However, this technique is a valuable and acceptable model for direct delivery of a compound to the CNS of humans using techniques such as intranasal delivery, injection into cerebral spinal fluid pathways and brain injection. Many animal models are unsuitable for use with humans but they still provide predictive value and benefit for humans.

Regarding undue experimentation, section 2164.06 of the MPEP states the quantity of experimentation needed to be performed by one skilled in the art is only one factor involved in determining whether "undue experimentation" is required to make and use the invention. "[A]n extended period of experimentation may not be undue if the skilled artisan is given sufficient direction or guidance." *In re Colianni*, 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977). " 'The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the

direction in which the experimentation should proceed.'" *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (citing *In re Angstadt*, 537 F.2d 489, 502-04, 190 USPQ 214, 217-19 (CCPA 1976)). Applicants submit that the specification provides a reasonable amount of guidance with regard to dosing strategies and methods. Also, the specification provides detailed examples using accepted animal models that are predictable for outcomes in human subjects. With the level of guidance provided in the application, any experimentation necessary to fine-tune dosing strategies would be merely routine and not undue.

Therefore, Applicants submit that the specification allows one of skill in the art to make and use the claimed invention without undue experimentation. Accordingly, applicants request removal of the rejection of claims 1 and 6 under 35 U.S.C. §112, first paragraph.

CONCLUSION

Applicants respectfully assert that claims 1 and 6 are thus allowable as amended herein, and request that a timely Notice of Allowance be issued in this case. If there are any remaining issues preventing allowance of the pending claims that may be clarified by telephone, the Examiner is requested to call the undersigned.

Respectfully submitted,

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